

II. REMARKS

Claims 1 to 15 are pending in the subject application. By this response, claim 10 is canceled without prejudice or disclaimer and claims 1 to 9 and 11 to 15 were amended. The claims have been amended to conform them to standard U.S. patent practice as requested by the Office. The amendments to the claims are not intended to be a dedication to the public of the subject matter of the claims as previously presented or the equivalents thereof. Support for the claims as amended can be found throughout the specification as filed. An issue of new matter is not raised by these amendments and entry thereof is respectfully requested.

In view of the preceding amendments and the remarks that follow, reconsideration and withdrawal of the rejections set forth in the outstanding Office Action is respectfully requested.

Rejections Under 35 U.S.C. § 112 Second Paragraph

The claims stand variously rejected under 35 U.S.C. § 112, second paragraph. In response to the Office's rejections and in compliance with the Office's suggestions, the claims have been amended in a sincere effort to remove the grounds for rejection. In view of the preceding amendments, reconsideration and withdrawal of the rejections are respectfully requested.

Rejections Under 35 U.S.C. § 102(b)

Claims 11-13 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by McAuliffe et al., of record, published February 1999 (vol. 2). The Office opined that McAuliffe et al. teach a concentrated lacticin 3147, which was dialyzed and precipitated from culture media supernatant. The Office remarked that as lacticin 3147 in any form, spray-dried or otherwise, is still the same compound, and is that which is claimed, the instant invention is anticipated by the

reference.

Claims 11 to 15 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Ryan et al. (WO 96/32482, a copy of which was provided to applicant with the International Search Report). The Office opined that Ryan et al. disclose the concentration and freeze-drying of lacticin 3147 (see pages 13-14) and that the use of lacticin 3147 in various food products is disclosed, including in vegetable and meat preparations, and canned foods, which are traditionally subjected to increased pressure over that of atmospheric pressure. (See claim 9 of the reference, for example.) The Office alleged that as lacticin 3147 in any form, spray-dried, freeze-dried or otherwise, is still the same compound, and is that which is claimed, the instant invention is anticipated by the reference.

Applicants respectfully traverse.

McAuliffe et al. describes a concentrated lacticin 3147 which was dialyzed and precipitated from culture media supernatant. The present invention describes the production of lacticin 3147 concentrate made by a different process and therefore having different physical properties, e.g., it that may be formulated as a spray-dried powder. Ryan *et al.* discloses freeze dried lacticin 3147 and its use in various food products. Lacticin 3147 is therefore known and thus Applicants agree that the preparation of a known product cannot be considered to be novel just because it is prepared in a different physical form. However, the lacticin 3147 disclosed in McAuliffe et al. is a product produced by bacterial growth in a complex nutrient medium which is suitable only as an analytical product and not as a food ingredient. It is not a commercial food additive. Furthermore, the product claimed is not lacticin 3147, it is a concentrate capable as a formulation as a spray-dried powder which is quite distinct from the product disclosed in McAuliffe et al.

No
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Thus, the cited references do not the invention of claims 11 to 15 and withdrawal of the rejections under 35 U.S.C. § 102 are respectfully requested.

Rejections Under 35 U.S.C. § 103(a)

Claims 1 to 15 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Ryan et al. (WO 96/32482), in view of DE 2616390 (English abstract provided). The Office noted that Ryan et al. WO '482 is taken as cited in the lack of novelty rejection. The Office argued that the reference also discloses the:

“growth of *Lactobacillus lactis* overnight on LMI7 (pg. 12), TY (pg. 13), and whole milk (pg. 7) fermentation broths, to produce lacticin 3147. The media was “supplemented with 0.5% glucose or lactose” (pg. 7). The cells were cultured at 30°C (mid-pg. 12, top pg. 13). At line 30 of page 5, it is stated that ‘since the biological activity of the bacteriocin of the present invention is similar to that of nisin, it could be used for similar applications.’”

The Office also noted that Ryan et al. at page 2, states that the bacteriocin nisin is also produced by strains of *Lactobacillus lactis*, as well as other bacteria.

DE 2616390 is alleged to disclose the production of a spray-dried “nisin-enriched milk powder”. Skim milk is inoculated with a nisin-producing bacterial culture, and fermented for 18 hours at a pH between 6.0 and 6.8, at 28 to 33 degrees C. The resultant media is cooled to 10 to 14 degrees C after fermentation, using a heat exchanger, concentrated to 14 to 25% solids, spray-dried at 87 to 97 degrees, and cooled as it leaves the drier.

Thus, the Office remarked that it would have been obvious to one of ordinary skill in the art to have produced lacticin 3147 in spray - dried powder form. Ryan et al. is alleged to specifically provide the connection between lacticin 3147 and the known bacteriocin, nisin. DE '390 is alleged to demonstrate known steps in the art for the culturing and production of bacteriocins powders, and that while the abstract of DE '390 does not teach the inactivation of the bacterial culture; however, as it teaches that this may be used in food products, it follows that

inactivation of the bacteria prior to such drying and use, would have been an obvious safety step, well-known in the art. The Office remarked that the particular parameters instantly claimed, such as the use of lactose to seed crystals, and heat inactivation of bacteria, were well-known and commonly practiced in the art, and would not have involved an inventive step for one of ordinary skill, given the specific teachings of the references and the common state of the art at the time the invention was made.

Applicants respectfully traverse. The process according to the present invention involves the production of a spray-dried lacticin 3147 concentrate. Claim 1 sets out the steps of the process according to the invention. The process differs from that described in the prior art. The Examiner has stated that due to the fact that DE 2616390 teaches a process for the formation of spray-dried nisin milk powder and Ryan et al. refers to the fact that the biological activity of the lacticin 3147 described in that document is similar to that of nisin, it would be obvious to adapt the process of DE 2616390 to form spray-dried lacticin 3147. However, it would not be obvious to a person skilled in the art that lacticin 3147 would be robust enough to withstand spray-drying. This is because many bacteriocins are heat labile, for example enterolysin and colicin, and in fact there is a class of bacteriocins which are called heat-labile bacteriocins. Additionally, it would not be obvious to a person skilled in the art that there was the possibility that concentrating and spray-drying would not result in a significant loss in lacticin 3147 activity. In particular, during the spray-drying process the inlet temperature is about 173°C and the outlet temperature is 80 to 90°C. It couldn't be predicted that lacticin 3147 could withstand these temperatures and survive the heat treatment steps involved in spray-drying. Further it could not be predicted that such a spray-dried powder could be produced since spray-drying could have caused heat denaturation of the bacteriocin bearing in mind that the lacticin 3147 is composed of two peptides, both of which are required for activity. Furthermore dehydration could irreversibly inactivate the bacteriocin. In relation to the Examiner's argument that DE 2616390 teaches that it is possible to spray-dry nisin, we would point out that nisin and lacticin 3147 have quite different molecular structures

(Lacticin 3147)
but not 3147
as 3147
was used for
1000 hrs.
WAP's
"potential failure"
connecting at
Pin test, refs
Show mechanical
effects of
subject
required

and so one could not predict lacticin 3147's heat stability based on observations of nisin. This would teach away from attempting to produce a spray-dried lacticin 3147 powder. Thus, the Applicants submit that the inventions of amended claims 1 to 9 and 11 to 15 are not obvious in the light of the teaching of the prior art cited.

Reconsideration and withdrawal of the rejections under 35 U.S.C. § 103 is respectfully requested.

III. CONCLUSION

Applicants respectfully request entry of the amendment and reconsideration of the claims. A notice of allowance is earnestly solicited. In the unlikely event that the transmittal letter is separated from this document and/or the Patent Office determines that an extension and/or other relief is required, Applicantst petition for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 50-1189**, referencing attorney docket no. 24005-7002. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

If a telephone interview would advance examination of the subject application, the Examiner is invited to telephone Antoinette Konski at 650-849-4950.

Please note that Applicants' attorney is now with the law firm of:

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Please forward all correspondence concerning the subject application to the undersigned at this address.

Respectfully submitted,

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Version of the Proposed Amendments to the Claims

with Markings to Show Changes Made

In the Claims:

1. (Amended) A process for the production of a [spray-dried] lacticin 3147 [powder] concentrate, for use as a food ingredient, comprising:
 - (a) inoculating a medium with a lacticin 3147-producing strain of bacteria;
 - (b) fermenting the inoculated medium;
 - (c) adjusting the pH of the fermentation within the range from about pH 6.3 to 6.7;
 - (d) inactivating the bacterial fermentate; and
 - (e) evaporating the fermentate of step (d) thereby producing lacticin 3147 concentrate for use as a food ingredient.
2. (Amended) A process as claimed in claim 1, wherein the medium of step (a) is selected from the group consisting of milk, [or] dairy-based powders, [including] demineralized whey powder, reconstituted skimmed milk powder, whey protein concentrate powder, pasteurised whole milk, Cheddar cheese whey, yeast powders, [or] and synthetic laboratory-type media [such as LM17 and TY broth.]
3. (Amended) A process as claimed in claim 1 or 2, wherein the [concentrate] evaporation step comprises cooling the fermentate of step (d), seeding it (of step (e)) [is cooled, seeded] with lactose at about 0.1% w/w and [allowed to crystallize] crystallizing at a cooling rate of about 1°C per hour.
4. (Amended) A process as [claimed in any preceding] in claim 1, wherein the inoculated medium of step (b) is fermented at about 30°C for about 6 to 24 hours.

5. (Amended) A process as [claimed in any preceding] in claim 1, wherein the pH of the fermentation is adjusted in step (c) to about pH 6.5.
6. (Amended) A process as [claimed in any preceding] in claim 1, wherein the fermentate of step (d) is inactivated by [pasteurization] pasteurization or ultra-high temperature treatment.
7. (Amended) A process as claimed in claim 6, wherein said pasteurization step comprises heating [if the fermentate is pasteurised, it is pasteurized] at about 72⁰C for about 15 minutes.
8. (Amended) A process as [claimed in any preceding] in claim 1, wherein [the fermentate of step (d) is] step (e) comprises evaporating said bacteria fermentate evaporated to about [6] 60⁰C to about 40% total solids.
9. (Amended) A process as [claimed in any preceding] in claim 1, [wherein the crystallised concentrate is spray-dried] further comprising the step of spray-drying the concentrate.
10. (Canceled) A process as claimed in any preceding claim substantially as described herein.
11. (Amended) A lacticin 3147 concentrate [powder whenever produced by a process as claimed in] produced by the process of any one of claims 1 to [10.] 9.
12. (Amended) Spray-dried lacticin 3147 having the ability to inhibit organisms which are not resistant to lacticin 3147, and [preferably] having an activity of greater than about 20,000 AU/ml [,preferably about 30,000 AU/ml, more preferably about 40,240 AU/ml].
13. (Amended) A food product comprising a spray-dried lacticin 3147 as claimed in claim 11 or claim 12 [or as produced by a process as claimed in any of claims 1 to 10].

14. (Amended) [A] The food product as claimed in claim [12] 13, wherein said product is selected from the group consisting of [which is selected from] an infant milk formulation, a sauce, a mayonnaise, a dessert, a custard, a tinned food [such as a vegetable or meat product], a yogurt, a soup [or] and a bakery product.

15. (Amended) A food product as claimed in claim 13 and 14, which has been subjected to increased hydrostatic pressure [,preferably in the range 150 to 800 MPa.].